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10/511,725

10/19/2004

Toshiro Omori

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07/01/2009

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

07/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,725

Applicant(s)

OMORI ET AL.

Examiner

Amy L. Clark

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 April 2009 has been entered.

Acknowledgment is made of the receipt and entry of the amendment filed on 13 April 2009 with the cancellation of claims 8-26.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 and 27-30 are currently under examination.

Claim Objections

Claim 1 is objected to because of the following informalities: The article is missing from the beginning of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-7 and are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "as is" in line 23 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102/103

Claims 1-7 and 27-30 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Omori et al. (N*) (newly reapplied as necessitated by amendment).

Omori teaches a method of obtaining a composition by subjecting residual liquid by-produced in the shochu-production using barley as a raw material and obtained by distilling the shochu to a solid-liquid separation to provide a liquid component, filtering the obtained liquid component to provide a clear liquid, concentrating the obtained clear liquid to provide a concentrated liquid, subjecting the concentrated liquid to absorption treatment by using a synthetic absorbent to provide an unabsorbed (non-adsorbed) fraction, and drying the obtained unabsorbed (non-adsorbed) fraction (See abstract and paragraph 0001). Omori teaches that the synthetic absorbent can be an aromatic system synthetic material or a methacrylic synthetic adsorbent material (See claim 5).

Omori further teaches that freeze drying is a suitable method of drying the non-adsorbed fraction (See paragraph 0014).

Although Omori does not expressly teach that the composition obtained by solid/liquid separation of shochu stillage contains the components claimed by Applicants nor does Omori expressly teach that the composition obtained is capable of treating or preventing the onset of alcoholic hepatopathy in a patient in need thereof, the claimed functional properties are inherent to the preparation taught by Omori. The method of making the composition taught by Omori is one and the same as disclosed in the instantly claimed invention of Applicants. Thus, the composition obtained by solid/liquid separation of shochu stillage taught by Omori, which recites the same method steps as claimed by Applicants to provide a product-by-process, inherently contains the components in the ranges claimed by Applicants, is inherently a pharmaceutical composition and inherently displays the properties claimed by Applicants. Therefore, the reference anticipates the claimed subject matter.

In the alternative, even if the claimed composition obtained by solid/liquid separation of shochu stillage is not identical to the composition taught by Omori with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the composition obtained by solid/liquid separation of shochu stillage taught by Omori is likely to intrinsically possess the same characteristics (including with respect to the instantly claimed functional effects) of the claimed particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed composition

obtained by solid/liquid separation of shochu stillage would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at *least prima facie* obvious, if not anticipated by the cited reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' claimed composition is different and, if so, to what extent, from that of the teachings of Omori. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Response to Arguments

Applicant's arguments concerning the USC 102 rejection above have been thoroughly considered but are not deemed persuasive of error in the rejection.

Applicants argue that the claims are drawn to product claims, not method claims and that Applicants have submitted a declaration to show how the composition obtained by Omori is different from that obtained by Applicants.

However, this is not found persuasive because while it is appreciated that the composition is not a method claim, the composition, as currently claimed, is a product obtained by a process. Therefore, the response to Applicants' arguments set forth in the previous Office Action were directed to both elements of the product-by-process claims, since the product clearly is obtained from the process recited in the product-by-

process claim. With regards to the declaration, please see the response below under "Response to Amendment". Since Applicants are not claiming the composition is obtained by reducing the composition prior to application to the column, nor do Applicants claim the type of adsorbent (according to Applicants' declaration, the type of material used to separate the shochu stillage after reduction appears to make a difference and Applicants assert this helps distinguish the invention from the prior art). As currently claimed, Applicants do not require these method steps as part of the product-by-process claims.

With respect to the declaration filed 04/13/2009 under 37 CFR 1.132, the declaration is not deemed sufficient to overcome the rejection of claims 1-7 and 27-30 based upon the rejection under 35 U.S.C. 102(b) as being anticipated by Omori et al. (N*) as set forth in the last Office action because: Applicants are claiming a composition comprising a range of different compounds obtained from subjecting barley shochu stillage to solid-liquid separation. However, the amounts of each compound measured by Applicants in the three different methods provided in Applicant's declaration are very similar, in terms of the amount of the amino acids, polysaccharides and free saccharides. Also, Applicants do not claim that the barley shochu stillage is condensed to 1/3 (presumably to 1/3 the volume, but that is not exactly clear) and the type of column used that Applicants assert makes a difference in the amounts of each compound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALC, Examiner AU 1655
June 29, 2009

/Christopher R. Tate/
Primary Examiner, Art Unit 1655